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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/528,593	05/24/90	VAN NEST G	343747/CHIR-0

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ART UNIT	PAPER NUMBER
189	4

DATE MAILED: 06/04/91

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire three month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☐ Claims 1-35 are pending in the application.
   Of the above, claims 10-28 and 31-35 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-9 and 29-30 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Claims 1-35 are pending in this application.

Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification, drawings and/or claims.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-9 and 29-30, drawn to an adjuvant composition comprising an oil and an emulsifying agent and a method of stimulating an immune response using the composition of claims 1-9 as an antigen classsified in Class 252, subclasses 351 and 352 and Class 424, subclass 88.

II. Claims 10-27 and 31-35 , drawn to the composition of Group I with additionally requires the presence of an immunostimulating agent and a muramyl peptide optionally attached to a phospholipid and a method of using said composition for immunostimulation, classified in Classes 424 and 514, subclasses 88 and 8 respectively.

III. Claim 28, drawn to a vaccine, classified in Class 424, subclass 88.

Groups I, II and III are separate and distinct each from the other and a reference which would render obvious under 35 U.S.C. 103 claims drawn to one invention would not render obvious any other invention-absent ancilliary teachings. It would be an undue burden to examine all of the inventions in one application.

Because these inventions are distinct for the reasons given

above examination purposes as indicated is proper.

During a telephone conversation with Richard Neely on 10/26/90 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-9 and 29-30. Affirmation of this election must be made by applicant in responding to this Office action. Claims 10-28 and 31-35 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Initially, it appears that claim 8 is inadvertantly dependent from claim 20. Correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure.

The specification is objected to regarding the terminology "a protective antigen" and the proportions of ingredients used in the adjuvant. Note "sufficient droplet size reduction can usually be effected by having the surfactant present in an amount of 0.02% to 2.5% by weight (w/w)." Therefore, the scope of the claims are not supported by the enabling disclosure.

Claims 1-9 and 29-30 are rejected under 35 U.S.C. § 112,

first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-9 and 29-30 are rejected under 35 U.S.C. § 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over EPO 315153.

The claimed subject matter relates to compositions comprising a metabolizable oil and an emulsifying agent and a method for stimulating an immune response.

The reference teaches an adjuvant composition and a method

of using the same comprising a metabolizable oil, an emulsifier (a non-toxic tetrapolyol) wherein the particle size of <0.1 uM to about 2.5 uM was obtained, formulation 3, pages 11-13. Because the claims are drawn to an adjuvant comprising the ingredients taught by the art and a conventional method of using the same, the claims are anticipated and/or rendered obvious in view of the art. The determination of the amount to use in the adjuvant composition and the conventional method of using the composition is well within the skill of an ordinary artisan in the art.

Claims 29-30 are rejected under 35 U.S.C. § 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Glass et al. (USP 3,919,411) or Cantrell (USP 4,803,070).

Either reference teaches a method of stimulating immune response in a host comprising administering an adjuvant and an antigen wherein the adjuvant is an emulsion system containing a metabolizable oil and a detergent. See the entire document. Because the claims are drawn to the subject matter taught by the art, the claims are anticipated and/or rendered obvious in view of the art.

Claims 1-9 and 29-30 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Prigal (USP 3,678,149).

The patentee discloses a method of enhancing the action of a medicament comprising administering an aqueous emulsion having an

average particle size of about 0.1-10 microns and containing a metabolizable oil (abstract) and an emulsifier (column 7, lines 32+). Because the claims are drawn to a subject matter taught by the art, the claims are anticipated (claims 1-3, 5, 7, and 29-30) and/or rendered prima facie obvious (claims 4, 6, 8, and 9) in view of the art. Determination of the particular emulsifying agent and the amount to use is well within the purview of the artisan.

Claims 1-9 and 29-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim of copending application Serial No. 07/357035. Although the conflicting claims are not identical, they are not patentably distinct from each other. The exclusion of polyoxypropylene-polyoxyethylene block copolymner does not give rise to patentaby distinctness.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

No unexpected or unobvious results are noted and the claims must be refused.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Kraus whose telephone number is (703) 308-4214.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN DOLL
SUPERVISORY PATENT EXAMINER
ART UNIT 189B

ejk EJK
May 30, 1991